

REMARKS/ARGUMENTS

Claims 1-6, 8-20 and 22-23 remain in this application.

Rejection Under 35 USC 112, First Paragraph

Claims 1-5, 8-12, 15-20, 22, and 23 were rejected under 35 USC 112, first paragraph. The Office Action asserts that “claims 1 and 22 lack written description because . . . the claim and specification because while the claims and the specification state that no more than a certain percent of water is left after drying at 105° C the time if which the dosage form is dried was not recited.” See Page 2 of the Office Action. Applicants respectfully disagree.

Claims 1 and 22 are not process claims, but rather both claims are directed to an immediate release compressed tablet dosage form. Claims 1 and 22 both recite that the “dosage form has a moisture content of not more than about 5 percent as measured by weight loss on drying at 105 degrees Celsius.” Thus, this limitation recites a physical characteristic of the dosage form (e.g., if the dosage form is dried at 105 degrees Celsius, the dosage form will not loose more than about 5% in weight). As stated in the previous response, the amount of time it takes for the weight of dried dosage form’s weight to normalize following drying at 105 degrees Celsius will obviously depend upon the formulation of the dosage form (e.g., the water content of the dosage form at room temperature). Thus, the time in which the dosage form is dried is the time it takes for the weight change, if any, to normalize at this temperature.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 USC 103

Claims 1-5, 8-12, 15-20, 22, and 23 were rejected under 35 USC 103(a) as being unpatentable over Buehler et al. (US6432442) in view of McTeigue et al. (US 2002/0031552) in view of Dressman et al. (US5789393). See Page 4-7 of the Office Action. According to the previous office action of August 15, 2007 (“Previous Office Action”),

“Buehler discloses a chewable pharmaceutical dosage form comprised by weight 1-20% gelatin, 10% hydrocolloid including HPC, up to 60% sweetener such as sorbitol and xylitol, [and] the matrix further contains 2-30% of a taste masked coated pharmaceutically active agent including ibuprofen. . . . Buehler does not disclose the exact taste masked coating as claimed by applicants and Buehler is silent on the MW and viscosity in 2% aqueous solution on the HPC matrix. McTeigue is used primarily for the disclosure within the taste masked pharmaceutical particles and chewable tablets made from those particles were well known in the art at the time of the invention . . . Dressman is used only to show that HPC within the MW and viscosity claimed by applicant was well known at the time of the invention. . . . Thus the claimed invention would have been

prima facie obvious because the substitution of one known element such as a coating material disclosed within McTeigue for another known element such as the coating materials disclosed within Buehler would have yielded predictable results to one of ordinary skill in the art at the time of the invention.”

See pages 5-6 of the Previous Office Action. Applicants again respectfully disagree.

As previously argued in the prior amendment of March 4, 2008 (“Prior Amendment”), the pending claims recite an immediate release compressed tablet dosage form “wherein said dosage form has a moisture content of not more than about 5 percent as measured by weight loss on drying at 105 degrees Celsius.” Buehler et al. fails to disclose, or suggest, such a dosage form. Rather, Buehler et al. discloses a chewable gelatin matrix dosage form, not a compressed tablet. As discussed on pages 1-2 of the specification of the present application:

[Buehler et al.] discloses the use of a gelatin matrix and an optional hydrocolloid as another technique for providing a soft, chewable delivery system. Because these “gummi” or confectionary systems also contain water in an amount of from about 10 to 30 percent by weight of the final product, they disadvantageously possess certain limitations with respect to shelf-life, packaging, and storage conditions. Additionally, it is economically more beneficial to produce other dosage forms such as, for example, compressed tablets, due to their simplicity of processing (emphasis added).

Specifically, Buehler et al discloses on col. 5, lines 18-22. “Water is used to hydrate both the gelatin and hydrocolloid, and makes up the remainder of the dry product weight. Water is present in the final product at levels of from about 10 to 30 weight percent, more typically, water is present at a level at about 20 to about 25 weight percent.” Thus, Buehler et al. does not teach a compressed tablet, nor does it teach a product comprising the claimed moisture content.

In response to this argument, the current Office Action asserts on pages 4-5 of the Office Action:

“the relevance of the above assertions is unclear . . . Regarding applicants assertion on the moisture content being no more than 5% after drying, it is important to note that the limitation does not actually state that the moisture content is not more then about 5% for the claimed composition . . . If the composition formed from the combination of references was dried to completion at 105°C the examiner concludes that the moisture content would be less than 5% since the composition is essentially the same as applications claimed composition and would therefore have the same drying properties. (emphasis added)”

The Office Action, however, provides no support for why one would so dry the compositions of Buehler et al. As discussed above, the composition of Buehler are “Gummi” confection that

contain a high amount of water. Why would one of ordinary skill in the art want to the water from these compositions?

The Office Action appears to be reading a process step into the composition claims of the present invention. For example, the Office Action states on page 5 “almost any conceivable composition when exposed to temperature of 105°C, which is of course higher than the bp of water would contain essentially little or no moisture if dried for extremely long periods of time.” Applicants again want to point out that the limitation is not a functional limitation, but rather is a means of stating that the claimed dosage forms have a low moisture content (e.g., the claimed compositions would only have a 5 percent weight loss on drying at 105 degrees Celsius). This would not be the case for the compositions of Buehler which would have a greater than 5 percent weight loss on drying at 105 degrees Celsius.

The Previous Office Action asserted that “since the use of HPC within applicants claimed MW range was already well known to be useful in pharmaceutical compositions as shown by Dressman applicants claimed HPC was a known option available at the time of the invention and someone of ordinary skill in the art would have high expectation of success in using the specific MW of HPC disclosed within Dressman and substitute those for the HPC disclosed with McTeigue.” Applicants again respectfully disagree.

While Dressman may disclose the use of such specific molecular weight of HPC as in the present invention, the reference does not disclose, or suggest, the use of such ingredient in a chewable tablet. The current Office Action asserts on page 6 that “since both references are at least related as pertaining to pharmaceutical formulations it would be expected that natural polymers that are the same such as HPC could be interchanged between the two references. Applicants, however, again do not agree with the assertion that someone of ordinary skill in the art would have a “high expectation of success” in using the ingredient in a compressed tablet.

Further, Applicants unexpectedly found benefits is using such an ingredient in the chewable compressed tablets of the present invention. As set forth on page 11, lines 3-13 of the specification of the present application:

We have unexpectedly found that the addition of high weight average molecular weight hydroxyalkylcellulose to the matrix results in a dosage form that delivers a good mouthfeel through a rapid viscosity build without an initial intense drying sensation of the mouth and without a subsequent excessive slimy or gummy feel during mastication. Although the increase in viscosity will depend upon several factors such as, for example, the amount and molecular weight of such hydroxyalkylcellulose used and the amount and type of active ingredient, generally the use of about 0.1 percent to about 25.0 percent of a 60,000 to about 5,000,000 MW hydroxyalkylcellulose based upon the total weight of the dosage form, will result in a viscosity increase during tablet mastication that is similar to that obtained using gums, but without the drying sensation and without the subsequent excessive slimy or gummy feel imparted by using conventional agents.

In response to these unexpected benefits, the Office Action states “the examiner notes that the above cited expected results is actually just a subjective analysis or opinion of the benefits . . . there is no actual evidence besides the above conclusionary statement.” Applicants respectfully disagree, as certainly mouthfeel, including drying sensation, is clearly a benefit, even if it not capable of being analytically measured.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP-5014/WEM.

Respectfully submitted,

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